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02/27/98

Substitute for form 1449A/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(use as many sheets as necessary)</i>				<b>Complete If Known</b>	
				Application Number	
				Filing Date	2/27/98
				First Named Inventor	BLUME, Richard S.
				Group Art Unit	
				Examiner Name	
Sheet	1	of	4	Attorney Docket Number	

TITLE: METHOD AND TEST KIT FOR ORAL SAMPLING & DIAGNOSIS

[illegible][illegible]

Examiner Signature	<i>Paul H. Wood</i>	Date Considered	8/12/1999
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<sup>1</sup> Unique citation designation number. <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

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Substitute for form 1449B/PTO		<b>Complete if Known</b>	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)		Application Number	09/031,578
		Filing Date	2/2/98
		First Named Inventor	BLUME, Richard S.
		Group Art Unit	
		Examiner Name	
Sheet 2 of 4	Attorney Docket Number		

TITLES: mechanical test kit for oral sampling &amp; diagnosis

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
Ph		SINGH, S. et al., "Determinants of esophageal 'alkaline' pH environment in controls and patients with gastroesophageal reflux disease," <u>Gut</u> , 1993 Mar; 34(3): 309-16	
		CHEN, M., et al., "Gastroesophageal reflux disease: correlation of esophageal pH testing and radiographic findings," <u>Radiology</u> , 1992; 185: 483-6	
		KAHRILAS, P., "Gastroesophageal reflux disease," <u>JAMA</u> , 1996 Sep. 25; 276(12): 983-8	
		SCHOEMAN et al., "Mechanisms of gastroesophageal reflux in ambulant healthy human subjects," <u>Gastroenterology</u> , 1995 Jan.; 108(1): 83-91	
		RICHTER, J., "Extraesophageal presentations of gastroesophageal reflux disease," <u>Semin. Gastrointest. Dis.</u> , 1997 Apr.; 8(2): 75-89	
		Wall Street Journal, "When your heartburn starts to linger after the holidays," December 29, 1997	
		WIENER, G., et al., "Chronic hoarseness secondary to gastroesophageal reflux disease: documentation with 24-hour ambulatory pH monitoring," <u>Am. J. Gastroenterol.</u> , 1989; 84(12): 1503-8	
		CONTENCIN, P., and NARCY, P., "Gastroesophageal reflux in infants and children: A pharyngeal pH monitoring study," <u>Arch. Otolaryngol. Head Neck Surg.</u> , 1992 Oct; 118: 1028-30	
		POPE, C., "Acid-reflux disorders," <u>N. Engl. J. Med.</u> , 1994 Sep 8; 331(10): 656-60	
		MEURMAN, J., et al., "Oral and dental manifestations in gastroesophageal reflux disease," <u>Oral Surg. Oral Med. Oral Pathol.</u> , 1994 Nov.; 78(5): 583-9	
Ph		SCHROEDER, P., et al., "Dental erosion and acid reflux disease," <u>Ann. Intern. Med.</u> , 1995 Jun. 1; 122(11): 809-15	

Examiner Signature	<i>Janet M. Wynn</i>	Date Considered	8/12/99
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Substitute for form 1449B/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet

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of

4

**Complete if Known**

Application Number	09/031,578
Filing Date	2/27/99
First Named Inventor	BLUME, Richard S.
Group Art Unit	
Examiner Name	
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**OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS**

Examiner Initials <sup>1</sup>	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
plw		MADINIER, I., et al., "Oral carriage of Helicobacter pylori: a review," <u>I. Periodontol.</u> , 1997 Jan.; 68(1):2-6	
		SCHINDLBECK, N., et al., "Which pH threshold is best in esophageal pH monitoring?" <u>Am. J. Gastroenterol.</u> , 1991; 86(9): 1138-41	
		ORR, W., et al., "The pattern of nocturnal and diurnal esophageal acid exposure in the pathogenesis of erosive mucosal damage," <u>Am. J. Gastroenterol.</u> , 1994 Apr.; 89(4): 509-12	
		JACOB, P., et al., "Proximal esophageal pH-metry in patients with reflux laryngitis," <u>Gastroenterology</u> , 1991; 100: 305-10	
		SHAKER, R., et al., "Esophagopharyngeal distribution of refluxed gastric acid in patients with reflux laryngitis," <u>Gastroenterology</u> , 1995; 109: 1575-82	
		VAEZI, M., and RICHTER, J., "Twenty-four hour ambulatory esophageal pH monitoring in the diagnosis of acid reflux-related chronic cough," <u>South Med. J.</u> , 1997 Mar.; 90(3): 305-11	
		KOUFMAN, J., and CUMMINS, M., "The prevalence and spectrum of reflux in laryngology: a prospective study of 132 consecutive patients with laryngeal and voice disorders," <u>Center for Voice Disorders of Wake Forest University</u> , 1997	
		LOCKE III, G., et al., "Prevalence and clinical spectrum of gastroesophageal reflux: A population-based study in Olmsted County, Minnesota," <u>Gastroenterology</u> , 1997; 112: 1448-56	
		ISOLAURI, J., et al., "Natural course of gastroesophageal reflux disease: 17-22 year follow-up of 60 patients," <u>Am. J. Gastroenterol.</u> , 1997 Jan.; 92(1): 37-41	
		OLDEN, K., and TRIADAFILOPOULOS, G., "Failure of initial 24-hour esophageal pH monitoring to predict refractoriness and intractability of reflux esophagitis," <u>Am. J. Gastroenterol.</u> , 1991; 86(9): 1142-6	
plw		JAMIESON, J., et al., "Ambulatory 24-hour esophageal pH monitoring: normal values, optimal thresholds, specificity, sensitivity, and reproducibility," <u>Am. J. Gastroenterol.</u> , 1992; 87(9): 1102-1110	

Examiner  
Signature

Paula Wingard

Date

Considered

8/12/99

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*note: method and test kit for oral Sampling & Diagnosis*

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<i>DR</i>		TEW, S., et al., "The illness behavior of patients with gastroesophageal reflux disease with and without endoscopic esophagitis," <u>Dis. Esophagus</u> , 1997 Jan.; 10(1): 9-15	
		BARDHAN, K., "Is there any acid peptic disease that is refractory to proton pump inhibitors?" <u>Aliment. Pharmacol. Ther.</u> , 1993; 7 Suppl 1: 13-24	
		SACHS, G., "Proton pump inhibitors and acid-related diseases," <u>Pharmacotherapy</u> , 1997 Jan-Feb.; 17(1): 22-37	
		SONTAG, S., et al., "Lansoprazole heals erosive reflux esophagitis resistant to histamine H2-receptor antagonist therapy," <u>Am. J. Gastroenterol.</u> , 1997 Mar.; 92(3): 429-37	
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		HAASE, G., et al., "A unique teletransmission system for extended four-channel esophageal pH monitoring in infants and children," <u>J. Ped. Surg.</u> , 1987 Jan.; 22(1): 68-74	
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		JOSHI, G., et al., "Continuous hypopharyngeal pH measurement in spontaneously breathing anesthetized outpatients: laryngeal mask airway versus tracheal intubation," <u>Anesth. Analg.</u> , 1996; 82: 254-7	
		AYRE, J., "The gargle test: new oral cancer screening method," <u>NY State Dent. J.</u> , 1972 Jun-Jul.; 38(6): 345-50	
<i>pu</i>		LOUGHLIN, C., and and KOUFMAN, J., "Paroxysmal laryngospasm secondary to gastroesophageal reflux," <u>Laryngoscope</u> , 1996, Dec.; 106(12 Pt. 1):1502-1505	

Examiner Signature	<i>Pamela J. Good</i>	Date Considered	8/12/99
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